Lineage Cell Therapeutics Announces Issuance of Patent Underlying Its AlloSCOPE™ 5D Manufacturing Platform

September 8, 2026

U.S. Patent No. 12,692,476 Has an Expected Expiration Date of June 9, 2043

CARLSBAD, Calif.--(BUSINESS WIRE)--Sep. 8, 2026-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel, allogeneic, “off the shelf”, cell therapies for serious medical conditions, today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 12,692,476, with claims covering the Company’s proprietary AlloSCOPE cell manufacturing platform (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent cell Engineering), including, its AlloSCOPE “5D” technology. AlloSCOPE 5D focuses on the production of high volume, low passage, undifferentiated and genetically stable pluripotent stem cells that can synchronously respond to differentiation cues in a seamless fashion. This approach is designed to offer greater control of differentiation than is normally available from traditional 2D or 3D manufacturing modalities, and we believe it can support large scale production of cell-based therapies for high dose indications like Type 1 Diabetes. The patent has an expected expiration date of June 9, 2043.

“This newly issued U.S. patent is a critical asset for Lineage because it underpins what we believe is a novel solution to two of the major obstacles to the commercialization of pluripotent cell-derived therapies,” stated Brian M. Culley, Lineage CEO. “Traditional methods for pluripotent cell expansion are based on either a 2D system, which allows for a synchronized production, but is limited by scale and mandatory manipulation, or a 3D system, which improves scale and reduces aseptic risk, but diminishes synchronicity and consistency. Lineage’s proprietary 5D method, that employs microcarriers as a 2D surface within a 3D bioreactor, can achieve the control and reproducibility of 2D expansion within the scale of a 3D system. This 5D approach may also allow for direct differentiation of cell-based product candidates with minimal handling, high levels of control, and reduced aseptic risk, and do so at a scale that could support very large dose requirements."

“The Lineage team has distinguished themselves by successfully releasing multiple batches of a cell-based product candidate in a clinical trial, with each batch derived from a GMP working cell bank that itself was derived from a GMP master cell bank (MCB). We believe that the expansion capability from the steps that Lineage has already successfully performed can generate millions of vials of “off the shelf” material from an MCB and that this production modality can yield production costs significantly below those of autologous cell therapies. We believe Lineage’s 5D technology has established a proprietary position to be able to provide commercially feasible production scale for indications with dose requirements as high as a billion cells per patient, such as is expected to be required for the treatment of Type 1 Diabetes. Lineage has already deployed AlloSCOPE 5D methods to support its corneal endothelial cell transplant program (COR1) and plans to continue to utilize AlloSCOPE 5D to support its ongoing development toward ILT1,” Mr. Culley concluded.

About the AlloSCOPE (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering) Platform
The AlloSCOPE (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering) platform highlights the key attributes of Lineage’s in-house technology and describes a differentiation and production modality from which Lineage can manufacture millions of doses of an allogeneic, cell-based product derived from a single initial pluripotent cell line, conferring consistent, cost-effective, and scalable cell-based production and which can be applied across multiple programs. From our proprietary AlloSCOPE platform, we successfully completed a current Good Manufacturing Practice (“cGMP”) production run from a custom, two-tiered cell banking system, featuring a genetically-stable master cell bank (MCB) created from a single, well-characterized pluripotent cell line, which generated a working cell bank (WCB), which then provided the source material for two final cell-based product candidates. AlloSCOPE “5D” describes an application of AlloSCOPE with the goal of higher scale production with reduced manipulation.

Allogeneic cell therapy product manufacturing generally involves three basic steps: (i) expansion of pluripotent cells; (ii) differentiation of cells into the desired cell type, and (iii) further expanding those cells prior to harvesting, filling and cryopreserving the final product. In cell therapy manufacturing, how cells are grown and organized during differentiation and/or expansion can affect their scalability, phenotype, process control, manufacturing cost, and the characteristics of the final product. In a 2D process, cells are typically grown as an adherent monolayer on a flat, coated surface, such as a culture flask or multilayer vessel. This method allows for close control of cell growth and morphology, but scaling generally requires increasing the number of culture vessels, which can add labor, facility space, cost, and process complexity. In a 3D process, cells are grown in a three-dimensional environment, often as aggregates or spheroids within a bioreactor. This method can support automation, higher cell densities, and greater scale from a smaller footprint, but requires a tradeoff of less control and loss of synchronization. Lineage’s AlloSCOPE 5D technology is the Company’s innovative process of merging 2D manufacturing with 3D scale. By creating 2D-like growth conditions within a controlled, scalable 3D environment, AlloSCOPE 5D is designed to address one of the central manufacturing challenges in large-scale cell therapy manufacturing, by harnessing the precision and uniformity advantages of 2D culture with the scalability, efficiency, and automation capabilities of 3D bioreactor systems, while simultaneously avoiding the scale limitations of 2D methods and unresolved challenges associated with aggregate-based 3D culture.

About Lineage Cell Therapeutics, Inc.
Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel allogeneic, or “off the shelf”, cell therapies for serious medical conditions. Lineage’s programs are based on its proprietary cell-based technology platform, AlloSCOPE™ (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering), and associated development and manufacturing capabilities. From this proprietary AlloSCOPE platform, Lineage develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or substantially identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages, and in some instances may be designed to have additional beneficial properties. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient’s functional activity. Lineage’s pipeline currently includes: (i) OpRegen ® cell therapy, a retinal pigment epithelial cell therapy in Phase 2a development

under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ReSonance® (ANP1), an auditory neuronal progenitor cell therapy in preclinical development under a collaboration with William Demant Invest A/S for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy research initiative being evaluated for development for the potential treatment of vision loss due to photoreceptor dysfunction or damage; (v) RND1, a novel hypoimmune induced pluripotent stem cell line being evaluated for development under a gene editing partnership; (vi) ILT1, a cell therapy manufacturing initiative focused on the issue of large-scale production of undifferentiated pluripotent cells, which if successful and applied to an islet cell differentiation protocol, could be evaluated for the production of islet cells to support a potential treatment of Type 1 Diabetes; and (vii) COR1, a corneal endothelial disease cell therapy in preclinical development for the potential treatment of corneal endothelial disease. For more information, please visit www.lineagecell.com or follow the company on X/Twitter @LineageCell.

Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "believe," "aim," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "suggest," or the negative version of these words and similar expressions. Such forward-looking statements include, but are not limited to, statements relating to: the design and expected benefits of the AlloSCOPE 5D manufacturing platform, including the belief that it can support large-scale production of cell-based therapies for high dose indications; the potential for AlloSCOPE 5D to allow for direct differentiation of cell-based product candidates with minimal handling, high levels of control, and reduced aseptic risk at a scale that could support very large dose requirements; the belief that Lineage's expansion capability can generate millions of vials of "off the shelf" material from a master cell bank and that this production modality can yield production costs significantly below those of autologous cell therapies; the belief that Lineage's 5D technology has established a proprietary position to provide commercially feasible production scale for indications with dose requirements as high as a billion cells per patient, such as may be required for the treatment of Type 1 Diabetes; plans to continue to utilize AlloSCOPE 5D to support ongoing development toward ILT1; Lineage's plans to, and its ability to, apply its manufacturing capabilities to establish a production modality that, if successful, and if paired with an islet-cell differentiation protocol, could potentially address manufacturing scale considerations relevant to potential future islet cell therapy product candidates and potentially solve a major hurdle to commercialization of islet cell therapy product candidates through its ILT1 manufacturing initiative; the potential of the AlloSCOPE platform, including based on prior success in completing production runs for two product candidates, to manufacture millions of doses of a cost-effective, scalable, and consistent supply of an allogeneic, cell-based product derived from a single initial cell line, that can be applied across multiple programs; the ability of Lineage's two-tiered cell banking system to generate millions of doses of final product; and the expected expiration date of U.S. Patent No. 12,692,476. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, but not limited to, the following risks: that the AlloSCOPE 5D manufacturing platform may not perform as designed and may not achieve the expected advantages over traditional 2D or 3D manufacturing modalities; that the AlloSCOPE 5D technology may not be able to support large-scale production of cell-based therapies for high dose indications at commercially feasible cost or scale; that integration of 2D growth conditions within a 3D environment may present unforeseen technical challenges; that Lineage may not be able to successfully generate millions of vials of material from a master cell bank or achieve production costs significantly below those of autologous cell therapies; that the expected patent expiration date may be subject to change based on patent term adjustments, terminal disclaimers, or other factors, and that patents may be challenged, invalidated, or circumvented by competitors; that Lineage's ILT1 development is in its early stages, and even if the AlloSCOPE 5D manufacturing initiative is successful in producing large-scale production of undifferentiated pluripotent stem cells, Lineage may not be able to successfully or feasibly differentiate those cells into islet cells, may not successfully establish a production modality for large-scale islet cell production, and there is no assurance that undifferentiated pluripotent stem cell manufacturing milestones will translate to clinical or commercial development or result in a viable product candidate for the treatment of Type 1 Diabetes; that the AlloSCOPE platform may not generate new programs with the speed, efficiency, or value creation potential that Lineage anticipates, and past development timelines may not be indicative of future results; that Lineage may not be able to manufacture sufficient clinical or commercial quantities of its product candidates in accordance with current good manufacturing practice; that the ongoing 2026 Iran War and broader Israeli regional conflict may materially and adversely impact clinical activities at Israel trial sites participating in the GAlette study and/or our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that development activities, preclinical activities, and clinical trials of product candidates may not commence, progress, or be completed as expected due to many factors within and outside of Lineage's control; that competing technologies and therapies may reduce or eliminate the commercial potential of Lineage's cell therapy product candidates and its AlloSCOPE 5D manufacturing platform; that regulatory requirements and changes in the regulatory landscape may delay, increase the cost of, or prevent Lineage from obtaining approval for its product candidates; and those risks and uncertainties inherent in Lineage's business and other risks discussed in Lineage's filings with the Securities and Exchange Commission (SEC). Lineage's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports with the SEC, including Lineage's most recent Annual Report on Form 10-K filed with the SEC and its other subsequent reports, which are available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

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